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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,770	06/19/2006	Holger Schmitt	PHDE030127US	7743
	7590 06/27/200 LLECTUAL PROPER	•	EXAMINER	
595 MINER ROAD CLEVELAND, OH 44143			BOR, HELENE CATHERINE	
CLEVELAND	OH 44143	·	ART UNIT	PAPER NUMBER
			3768	
•				
			MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Annlicont/o\				
	Application No.		Applicant(s)			
Office Action Summary	10/553,770	SCHMITT ET AL.				
Office Action Summary	Examiner	Art Unit				
The MAILING DATE of this communication	Helene Bor	th the correspondence address	· · · · · · · · · · · · · · · · · · ·			
Period for Reply	appears on the cover sheet wi	n the correspondence address	•			
A SHORTENED STATUTORY PERIOD FOR REWHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory per  - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the material patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC 1.136(a). In no event, however, may a re- tiod will apply and will expire SIX (6) MON tutte, cause the application to become AB	CATION.  Poly be timely filed  THS from the mailing date of this communication  ANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 19	9 October 2005.					
	his action is non-final.					
3) Since this application is in condition for allo	wance except for formal matte	ers, prosecution as to the merits	is			
closed in accordance with the practice unde	er <i>Ex parte Quayle</i> , 1935 C.D	. 11, 453 O.G. 213.				
Disposition of Claims						
4) Claim(s) 1-12 is/are pending in the application	on.					
4a) Of the above claim(s) is/are without	Irawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-12</u> is/are rejected.						
	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and	d/or election requirement.	•				
Application Papers						
9) The specification is objected to by the Exam	iner.					
10)⊠ The drawing(s) filed on <u>19 October 2005</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) ☐ The oath or declaration is objected to by the	Examiner. Note the attached	Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of:  1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the papplication from the International Bur * See the attached detailed Office action for a	ents have been received. ents have been received in A riority documents have been eau (PCT Rule 17.2(a)).	pplication No received in this National Stage				
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 10/19/2005.	Paper No(s	iummary (PTO-413) )/Mail Date Iformal Patent Application 				

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### **DETAILED ACTION**

# Acknowledgement of Preliminary Amendments

1. For the record, acknowledgement is made of the applicant's preliminary amendments to the claims, 1-12, under 37 CFR 1.115. Under examination are the newly amended claims, 1-12.

## Specification

2. The disclosure is objected to because of the following informalities: Missing appropriate headings. Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (a) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.

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(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

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## Claim Objections

- 1. Claim 1-12 are objected to because of the following informalities: In Claim 1 Line 14, "the time-dependent concentration of contrast agent" lacks antecedent basis. In Claim 1 Line 24, "the X-ray absorption" "lacks antecedent basis. Numerous other lack of antecedent basis rise throughout the claims. The applicant is advice to fully review the claims and resolve the objections. Appropriate correction is required.
- 2. Claim 8 is objected to because of the following informalities: Part C 2<sup>nd</sup> line reads, "SECG" this appears to be a typo. The examiner will interpret the claim to read ECG for the purpose of the office action. Appropriate correction is required.
- 3. Claim 11 is objected to because of the following informalities: On the 2<sup>nd</sup> to 3<sup>rd</sup> line, "at at". Appropriate correction is required.

# Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claim 1, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicant appears to be using the terms "time-dependent concentration of contrast agent" and "time-dependent distribution of contrast agent" interchangeably. For example in Claim 1 on lines 9, 14, 25 and the last line.
- 6. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 2 is a method claim that depends from a device claim, making Claim 2 improper. Applicant will need to either amend or cancel the claim.

7. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. On the first line of Claim 9, "wherein first the second set of X-ray projection images" is improper. It is unclear if the applicant is claiming the first set or the second set of images. The examiner has interpreted the claim to read on the second set.

## Claim Rejections - 35 USC § 103

- 8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 9. Claim 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koppe'235 et al. (US Patent No. 6,442,235 B2) and further in view of Wink et al. (US Patent No. 7,180,976 B2).
- Claim 1, 7 & 8: The claims are examined as best understood by the examiner. Koppe'235 teaches an X-ray imaging device with computer means (Figure 1, Element 12, 13, 16 & 19 [Col. 4, Line 23-27]). Koppe'235 teaches a device for visualizing the blood flow in a coronary vascular tree of a patient (Col. 1, Line 29-37 & Col. 4, Line 23-

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27). Koppe'235 teaches the visualization (Figure 1, Element 18) is effected based on data which contain a first set of X-ray projection images of the vascular tree in various phases of the heart cycle (Figure 1, D<sub>1</sub>...D<sub>m</sub>) and a second set of X-ray projection images (Figure 1, E<sub>0</sub>...E<sub>i</sub>...E<sub>n</sub>) recorded during or after the administration of a contrast agent (Col. 6, Line 3-13). Koppe'235 teaches computer means (Figure 1, Elements 15, 16 & 19) comprise a program control (Figure 1, Element 17), which operates in accordance with determining the time-dependent concentration [distribution] of contrast agent within the three-dimensional structure of the vascular tree (Col. 4, Line 35-37 & Claim 10). Koppe'235 teaches reconstruction of the three-dimensional structure of the vascular tree during the various phases of the heart cycle using the first set of X-ray projection images and splitting of the structure into a number of vascular segments (Col. 4, Line 40-55). Koppe'235 teaches determining the time-dependent concentration [distribution] of contrast agent within the reconstructed three-dimensional structure of the vascular tree (Col. 2, Line 50 – Col. 3, Line 11). Koppe'235 teaches finding local image areas assigned to the individual vascular segments within the X-ray projection images of the second set corresponding to the spatial positions of the vascular segments (Claim 10). Koppe'235 teaches determining the concentration of contrast agent within the vascular segments by evaluating the X-ray absorption within the local image areas (Col. 1, Line 56-60). Koppe'235 teaches the visualization of the flow of contrast agent through the three-dimensional structure of the vascular tree according to the time-dependent distribution of contrast agent (Claim 10 & Figure 1, Element 18). Koppe'235 fails to teach the ECG gating of the X-ray imaging device. However,

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Wink'976 teaches the assignment of the X-ray projection images of the second set to a respective phase of the heart cycle using the recorded second ECG (Col. 4, Line 16-23 & Col. 5, Line 3-6). It would have been obvious to one of ordinary skill in the art to combine the teachings of Koppe'235 and Wink'976 in order to improve volumetric reconstruction (Col. 7, Line 3-13).

Claim 2/1: The claims are examined as best understood by the examiner. Koppe'235 teaches an X-ray imaging, wherein the second set of X-ray projection images is recorded during or after the administration of the contrast agent, while the vascular tree fills with contrast agent and then the first set of X-ray projection images is recorded after the vascular tree is completely filled with contrast agent (Col. 6, Line 3-13).

Claim 3/1: Koppe'235 teaches an X-ray imaging device, with means for generating the first and the second set of X-ray projection images of the coronary vascular tree of the patient under various projection directions (Col. 1, Line 18-28). Koppe'235 fails to teach the ECG gating of the X-ray imaging. However, Wink'976 teaches the means for recording the ECG of the patient during the recording of the first and second sets of X-ray projection images (Col. 4, Line 16-23 & Col. 5, Line 3-6). It would have been obvious to one of ordinary skill in the art to combine the teachings of Koppe'235 and Wink'976 in order to improve volumetric reconstruction (Col. 7, Line 3-13).

Claim 4/2/1: Koppe'235 teaches an X-ray imaging device, wherein the computer means are arranged such that during or after the administration of the contrast agent

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first the second set of X-ray projection images is recorded while the vascular tree fills with contrast agent, and then the first set of X-ray projection images is recorded, after which the vascular tree completely fills with contrast agent (Col. 7, Line 11-19).

Claim 5/2/1: Koppe'235 teaches an X-ray imaging device, wherein the computer means (Figure 1, Element 17) are further arranged such that the recording of the first and/or second set of X-ray projection images is effected at a plurality of projection angles by means of continuous rotation-X-ray imaging (Col. 1, Line 18-28).

Claim 6/1: Koppe'235 teaches an X-ray imaging device, wherein the computer means are arranged such that for reconstructing the three-dimensional structure of a computer-aided modeling of the vascular tree is effected while eliminating the other anatomical structures contained in the first set of X-ray projection images (Col. 6, Line 22-31).

Claim 9/8: The claims are examined as best understood by the examiner.

Koppe'235 teaches an X-ray imaging method, wherein the second set of X-ray projection images is recorded during or after the administration of the contrast agent, while the vascular tree fills with contrast agent and then the first set of X-ray projection images is recorded after the vascular tree is completely filled with contrast agent (Col. 6, Line 3-13).

Claim 10/8: Koppe'235 teaches an X-ray imaging method, wherein the recording of the first and/or second set of X-ray projection images is effected using continuous rotation-X-ray imaging at a plurality of projection angles (Col. 1, Line 18-28).

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Claim 11/8: Koppe'235 teaches an X-ray imaging method, wherein the recording of the second set of X-ray projection images is effected at least one fixed projection angle (Claim 11).

Claim 12/8: Koppe'235 teaches an X-ray imaging method, wherein a computer-aided modeling of the vascular tree, with elimination of other anatomical structures contained in the first set of X-ray projection images (Col. 6, Line 22-31), is effected to reconstruct the three-dimensional structure (Col. 2, Line 38-40).

#### Conclusion

- 10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
  - a. Miyazaki; Mitsue et al. MR imaging using ECG-prep scan, 10/05/2004. US 6801800 B2.
  - b. Op De Beek; Johannes Catherina Antonius et al. METHOD AND APPARATUS FOR THREE-DIMENSIONAL IMAGE-RENDERING OF A SPATIAL AND TISSUE-BASED CONFIGURATION THROUGH SEPARATING HIGH CONTRAST AND INJECTED CONTRAST AGENTS IN MULTI-ANGULAR X-RAY ABSORPTION MEASUREMENT, 04/02/2002. US 6366635 B1.
  - c. Pesque, Patrick Rene. ULTRASONIC DIAGNOSTIC IMAGING SYSTEM WITH SCANHEAD ELEVATION BEAMFORMING, 04/18/2002. US 20020045820 A1.
  - d. Rasche; Volker et al. X-ray imaging method and a 3D-rotational X-ray apparatus for applying this method, 10/25/2005. US 6959067 B2.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb

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